

1 BY MR. BATES:

2 Q Well, go up to the top of page 3. The  
3 first -- they are talking about cases of clinical  
4 failure. They say there were two with the  
5 Ciprofloxacin, one resistant and one susceptible. Is  
6 that correct?

7 A Let's see. One of these patients, the  
8 sentence -- for 7 days, having -- on admission that was  
9 resistant. The same isolate was subsequently isolated  
10 2 days after Ciprofloxacin therapy was initiated. And  
11 Ciprofloxacin-susceptible species was isolated from the  
12 other patient at admission. That patient's illness  
13 lasted four days.

14 I'm not sure -- is this -- that was a  
15 susceptible, it lasted four days.

16 JUDGE DAVIDSON: All right. Excuse me.

17 THE WITNESS: Okay.

18 JUDGE DAVIDSON: We'll go off the record.

19 Read that over carefully and --

20 (A brief recess was taken.)

21 JUDGE DAVIDSON: We're back on the record.

22 MR. BATES: Your Honor, maybe it would assist

Corrected as per OR 46 6/13/03

825

1 if I -- we wrote some numbers on the chart --

2 JUDGE DAVIDSON: Well, if you're just refer --  
3 she's -- it's not the numbers that are the problem,  
4 it's the fact that you're referring -- you say the top  
5 of page 3. I look at the top of page 3 and I see -- on  
6 the right-hand column -- they recovered within 48  
7 hours. And you say it says two and one. I don't -- I  
8 can't follow you.

9 MR. BATES: At the top of page 3 there were no  
10 cases of clinical failure with ~~Aithromycin~~ <sup>azithromycin</sup> and only two  
11 with ~~Ciprofloxacin~~ <sup>ciprofloxacin</sup>.

12 JUDGE DAVIDSON: Oh, and you're looking at --  
13 I'm looking at a different exhibit than you have.  
14 That's --

15 MR. BATES: It's G-354, page 3. The top of  
16 the right column.

17 JUDGE DAVIDSON: Okay, I have a different  
18 exhibit then. So if that's the problem -- it says G-  
19 354, page 3. The top of the right-hand column starts  
20 with "<sup>Recovered</sup>~~Recovery~~ within 48 hours."

21 MR. BATES: That's correct. And the -- if I  
22 may, the second sentence -- the next sentence following

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Corrected as per OR 46 6/13/03

826

1 that, it says there were no cases of ~~Azithromycin~~ <sup>azithromycin</sup>  
2 failure in the ~~Azithromycin~~ <sup>azithromycin</sup> group, and only two  
3 failures -- in the ~~Ciprofloxacin~~ <sup>ciprofloxacin</sup> group.

4 JUDGE DAVIDSON: Go ahead. If the witness can  
5 follow you, it's okay with me. I'm having -- talk  
6 about that when you're ready.

7 THE WITNESS: Okay. So -- are you going to be  
8 talking about -- there's two failures. There's one  
9 susceptible, one resistant, among the failures. Is  
10 that correct?

11 BY MR. BATES:

12 Q Correct.

13 A Okay. Now what do I have to -- what -- is it  
14 about the four out of seven and the two out of seven --

15 Q We will get to that in a moment.

16 A Okay.

17 Q If you look at page 2, left hand column, just  
18 about where it says, "Laboratory studies." Do you see  
19 the definition of treatment failure?

20 A Yes. "Treatment was considered a failure if  
21 diarrhea or any symptom persisted for more than 72  
22 hours after treatment was initiated."

1 Q So would you agree with me, using that  
2 definition, that we have seven susceptible cases, seven  
3 resistant cases? Yes?

4 Yes, we're on page 3, right-hand column.

5 MR. SPILLER: Objection. We're in a chase  
6 for "doesn't it say," and I'm willing to stipulate it  
7 says what it says. But I think it's painful and  
8 unproductive, so I object to asking the witness doesn't  
9 the exhibit say something.

10 MR. BATES: I think the purpose of the  
11 question is to clarify how we understand this paper.  
12 There's obviously some confusion about what this paper  
13 says. I'm simply trying to see if I can get an  
14 understanding between the witness and myself about an  
15 inference to be drawn from what's said in this paper.

16 MR. SPILLER: Then the objection is beyond the  
17 scope of direct, because I don't think what this paper  
18 says is in the direct testimony that we're about cross-  
19 examining here.

20 JUDGE DAVIDSON: I'm going to sustain the  
21 objection. Move on.

22 Do you need some additional time, Mr. Bates?

1 MR. BATES: I just have one more -- one more,  
2 Your Honor. It should be short.

3 JUDGE DAVIDSON: I just asked if you needed  
4 time before you ask your next question. You can have  
5 it if you want it.

6 MR. BATES: No, no --

7 JUDGE DAVIDSON: Okay, go ahead.

8 BY MR. BATES:

9 Q Now when you worked with the EPA microbial  
10 risk assessment, did you become aware of what the  
11 population risk threshold was that EPA used for  
12 microbial -- in water?

13 MR. SPILLER: Object to the question as it's  
14 beyond the scope of written direct. The witness  
15 mentioned that work as a part of her qualifications.  
16 She did not include in her written direct testimony  
17 content, conclusions, or compilations of that research.

18 JUDGE DAVIDSON: Well, I'll listen to what you  
19 have to say in response to the objection. If it's  
20 preliminary to something else, I'll allow it. I'll  
21 have to see what we're talking about.

22 MR. BATES: Your Honor, there is a population

1 risk for campylobacter infections, based on this  
2 calculation we just went through. I'm trying to  
3 understand the relationship between that population  
4 risk and the risk that is used to judge what is safe in  
5 other contexts.

6 JUDGE DAVIDSON: I'm sorry, I didn't hear what  
7 you just said. It's safe in what?

8 MR. BATES: Safe in other contexts.

9 JUDGE DAVIDSON: Other contexts?

10 MR. BATES: In water. That's with a  
11 population risk --

12 JUDGE DAVIDSON: Well, how does that pertain  
13 to her testimony, that's what I want to know.

14 MR. BATES: We're trying to understand what is  
15 the significance of whatever number falls out --  
16 because of this -- whether it's -- whether it can be  
17 calculated --

18 JUDGE DAVIDSON: You've been doing that for  
19 quite some time, trying to understand that, haven't  
20 you?

21 MR. BATES: This time I'm trying to put it in  
22 a context of having --

Corrected as per OR 46 6/13/03

830

1 JUDGE DAVIDSON: Oh, well, one or two  
2 questions; but if you can't get succinct answers from  
3 the witness, you're just going to have to stop.

4 BY MR. BATES:

5 Q Ms. Bartholomew, do you recall roughly the  
6 population risk that you calculated for the U.S.  
7 population? The risk assessment was about 1 in 33,000  
8 or 34,000?

9 MR. SPILLER: The form of the question -- and  
10 the population risk you are describing is water, or  
11 mice, or Ciprofloxacin?

12 MR. BATES: Like I said, in their risk  
13 assessment, so we're talking the population risk  
14 resulting from risk calculation and --

15 JUDGE DAVIDSON: Exhibit numbers. That's --  
16 pointing to that chart, it's just confusing in the  
17 record.

18 MR. BATES: It is Exhibit <sup>B-953</sup>~~9433~~.

19 JUDGE DAVIDSON: Thank you.

20 BY MR. BATES:

21 Q Do you have a Table <sup>I</sup>~~2~~.2?

22 A Yes. And did you frame the question in terms

Corrected as per OR 46 6/13/03

831

1 of the population?

2 Q Yes.

3 A Okay. So that's the Table 5.2 --

4 Q I think it's <sup>I</sup> 2.2, is that right? On page 14.

5 A On page 14. I'm sorry, I was looking --

6 Q What page are you looking at?

7 A I'm looking at page 79.

8 Q That's the same page.

9 A Okay. For the general U.S. population, the  
10 mean in 1998 was ~~21~~ <sup>1</sup> in 34,945; and in 1999, it was 1 in  
11 32,912.

12 Q Is that about 3 in 100,000?

13 A I would say yes.

14 Q Do you know if the population risk that EPA  
15 uses for say drinking water is 1 in 10,000?

16 MR. SPILLER: Object. Relevance and beyond  
17 the scope.

18 JUDGE DAVIDSON: I'll let her answer, if she  
19 knows.

20 THE WITNESS: I have heard the number 1 in 10  
21 to the fourth for some things. I can't say  
22 specifically whether it was for that.

*Corrected as per OR 46 6/13/03*

832

1 MR. BATES: Well, I think -- just one moment.

2 JUDGE DAVIDSON: Certainly.

3 MR. BATES: I think that's all I have.

4 JUDGE DAVIDSON: All right. We'll take a  
5 short recess and we'll change places for redirect --  
6 unless you don't have any.

7 MR. SPILLER: Your Honor, I believe it's  
8 possible we don't have any, but I need to consult  
9 with --

10 (A brief recess was taken.)

11 JUDGE DAVIDSON: Say it again.

12 MR. SPILLER: Thank you, Your Honor. No  
13 questions on redirect.

14 JUDGE DAVIDSON: All right. The witness is  
15 excused.

16 I think this would be a good time to break for  
17 lunch, and we will return back and allow you to cross-  
18 examine Dr. Cox, who I see is here today, even though  
19 he's scheduled for tomorrow. Thank you for coming.

20 *NICHOLAS*  
MR. SPILLER: I would just like to add that  
21 Dr. Cox arrived at 1:30 this morning, so could we have  
22 a short session?

1 JUDGE DAVIDSON: Oh, okay, gee, I don't expect  
2 to finish it this afternoon. We might wait till 10:00  
3 tomorrow, now. He's tired. In fact, I'll state for  
4 the record at this time, and if you ask me, I'll repeat  
5 it again, if Dr. Cox feels that his cross-examination  
6 is too tiring, we can adjourn whenever he's tired, if  
7 it's a convenient place for counsel. And we can  
8 reconvene tomorrow morning.

9 Right now, is an hour sufficient for lunch, or  
10 do you need more? Okay, we'll adjourn until 12:35.

11 (Whereupon, at 11:35 a.m., a luncheon recess  
12 was taken.)  
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Corrected as per OR 46 6/13/03

834

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A F T E R N O O N   S E S S I O N

(12:34 p.m.)

JUDGE DAVIDSON: We're on the record.

MR. NICHOLAS: Just momentarily, Your Honor?

JUDGE DAVIDSON: Mr. Spiller, are you handling  
this one?

MR. SPILLER: Yes, Your Honor.

JUDGE DAVIDSON: Are we ready?

MR. SPILLER: After we get a witness, yes,  
Your Honor.

JUDGE DAVIDSON: Okay, let's put Dr. Cox on  
the stand.

MR. NICHOLAS: Bayer calls Louis Anthony Cox  
to the stand, please.

Whereupon,

LOUIE COX, JR.

was called as a witness and, having been first duly  
sworn, was examined and testified as follows:

JUDGE DAVIDSON: All right, please be seated.  
Give your full name and address to your counsel and  
then see what happens.

THE WITNESS: I am <sup>Louis</sup>~~Louie~~ Anthony Cox, Jr., of

1 Cox Associates, 503 Franklin Street, Denver, Colorado  
2 80218.

3 MR. NICHOLAS: Thank you, Dr. Cox.

4 May I approach the witness, Your Honor?

5 JUDGE DAVIDSON: Certainly.

6 MR. NICHOLAS: Your Honor, I'm about to hand  
7 Dr. Cox a document which I'm going to ask him to  
8 identify. It's B-1901. It is Mr. Cox's personal copy  
9 and has several mostly page notations on there. I'd  
10 like to use this copy, if I might, and we'd be happy to  
11 show it to counsel.

12 DIRECT EXAMINATION

13 BY MR. NICHOLAS:

14 Q Dr. Cox, could you identify this document,  
15 please?

16 A Yes, this is my written direct testimony.

17 Q And would you read the exhibit number, please,  
18 the bottom right-hand corner?

19 A It's Exhibit B-1901.

20 Q And would you turn to page 8, please, page 8  
21 of your testimony?

22 A Page 8, um-hmm. Yes.

1 Q And can you identify the signature there?

2 A That is my signature.

3 Q Thank you, Dr. Cox.

4 MR. NICHOLAS: I have no further questions,  
5 and we're ready for cross-examination.

6 JUDGE DAVIDSON: All right, do you understand  
7 what he was saying about the penciled notations on  
8 that?

9 MR. SPILLER: Not yet, but I hope to ask some  
10 questions about it, Your Honor.

11 JUDGE DAVIDSON: Well, would you like to look  
12 at it first, or have you seen it?

13 MR. SPILLER: That was going to be my first  
14 question.

15 CROSS-EXAMINATION

16 BY MR. SPILLER:

17 Q Dr. Cox, may I see the copy of your testimony  
18 and the annotations?

19 A Certainly, you may.

20 Q Thank you.

21 MR. SPILLER: May I have a moment, Your Honor?

22 JUDGE DAVIDSON: Certainly.

1 MR. SPILLER: Thank you, Your Honor.

2 JUDGE DAVIDSON: All right. Before we  
3 proceed, to avoid any confusion, because I certainly  
4 have a little bit here, my copy of Dr. Cox's testimony,  
5 page 1 is page 2, or maybe it's page 2 that's page 1.  
6 So I'll put the burden on you, Mr. Spiller, to make  
7 sure that we're talking about the same page. Use the  
8 numbers in the lower right-hand corner of the exhibit,  
9 so that everybody -- so that I can be on the same page  
10 that you're on, if you ask questions about the exhibit.

11 MR. SPILLER: Yes, Your Honor. And to clarify  
12 for me, I didn't observe that problem until later on in  
13 the attachment. You aren't literally speaking of pages  
14 1 and 2, but of subsequent pages that have discrepant  
15 numbers?

16 JUDGE DAVIDSON: No, the first page of the  
17 exhibit in mine is blank. And what shows as page 2 on  
18 my computer is page 1 on the exhibit.

19 MR. SPILLER: Then we do, indeed, have a  
20 discrepancy, Your Honor, and perhaps some questions  
21 from Dr. Cox -- we now have two problems to address.

22 JUDGE DAVIDSON: All right.

1 BY MR. SPILLER:

2 Q Dr. Cox, on the copy of your testimony that  
3 you have, am I correct that in addition to the page  
4 cross-references that your counsel mentioned, there are  
5 a number of interlineations, insertions of words,  
6 letters, I assume cross-references, that you've  
7 inserted in there?

8 A Yes, this is a -- a copy I marked up on the  
9 plane. It has two main kinds of insertions. One is  
10 where the PFOF responses from CVM raised questions or  
11 showed need for clarifications. The other is, since  
12 there are no hyperlinks in this document as there were  
13 in the original, I put page numbers next to several  
14 places so that I can quickly find the supporting  
15 analysis.

16 Q Thank you, Dr. Cox.

17 MR. SPILLER: Your Honor, to make sure that  
18 we're all playing from the same deck, so to speak, I  
19 request that during the cross-examination, we let the  
20 witness work from a copy more similar to ours without  
21 those notations. His counsel can hold your copy and  
22 when the circumstances are appropriate, we can discuss

1 on the record what information we need to get from it?

2 JUDGE DAVIDSON: Okay.

3 MR. SPILLER: Is counsel going to provide a  
4 copy to Dr. Cox?

5 MR. NICHOLAS: If you have a clean copy of his  
6 testimony, I think that would probably be the best  
7 one --

8 MR. SPILLER: I don't.

9 I apologize, Your Honor, for the delay. If  
10 you want to look at this, you don't have any notes in  
11 it that you know of, right?

12 BY MR. SPILLER:

13 Q Now, to attend to the problem that the Court  
14 pointed out, Dr. Cox, referring to the lower right-hand  
15 corner of Exhibit B-1901 that you have, is there a  
16 small word "page" followed by the numeral "1" on the  
17 very top page?

18 A Yes, there is.

19 Q And on the second through fifth pages --

20 A 2 through 5.

21 Q And is there only one page number on each of  
22 those pages?

1           A     Yes, that's correct. In fact, that's also  
2 true for 6, 7 and 8.

3           Q     And just for comparison, let's figure where  
4 the pagination separates. If you look at B-1901  
5 attachment 1, that has page 9 on the exhibit stamp and  
6 no number on the page, am I correct?

7           A     Yes, starting on page 9 of the exhibit stamp,  
8 that's correct.

9           Q     And then on page 10 of the exhibit stamp,  
10 there is a typed number 2 beneath that?

11          A     Or the Microsoft Word 2, yes.

12          Q     In my questions to you, I will refer to the  
13 exhibit stamped number, the small number that follows  
14 right after the term Exhibit B-1901.

15          A     All right, so I can just add eight to  
16 Microsoft Word. That will work.

17          Q     Or you can just rely on the exhibit, which is  
18 what I will do.

19          A     Okay.

20          Q     And now I need to straighten myself out with  
21 the Court's record, because it may be that the scanning  
22 has somehow introduced different pagination.

Corrected as per OR 46 6/13/03

841

1 MR. SPILLER: Your Honor, did I hear you  
2 correctly that your electronic version has a numeral 2  
3 on the very first page of his testimony.

4 JUDGE DAVIDSON: Yes. But it says it's a  
5 docket stamp number. So the --

6 MR. SPILLER: Let me check.

7 JUDGE DAVIDSON: The docket stamp number is  
8 number 1. So if we use the docket stamp number, we'll  
9 be on the same page. It's just that for some reason  
10 they've got a cover sheet on ~~her~~<sup>him</sup> that they've labeled  
11 as number 1.

12 MR. SPILLER: I'm afraid you will notice that  
13 with several of the exhibits that are in the electronic  
14 versions, Your Honor. And if it's acceptable, I will  
15 continue to refer to the docket stamp number.

16 JUDGE DAVIDSON: I think we will all be on the  
17 same page with that.

18 MR. NICHOLAS: I agree, Your Honor. These are  
19 all sequentially numbered.

20 JUDGE DAVIDSON: Okay, thank you.

21 MR. SPILLER: We are all on the same page now,  
22 so to speak.

1 BY MR. SPILLER:

2 Q Good afternoon, Dr. Cox. I am Robert Spiller  
3 with the Center for Veterinary Medicine. If any of my  
4 questions are not clear, I'll trust you to stop me to  
5 make sure that we have a good understanding about the  
6 question being answered.

7 In your testimony, I noticed that your  
8 signature occurs at page 8 of 95, and that limits your  
9 declaration that it is true and correct to the  
10 foregoing material. Do you now adopt pages 9 through  
11 95 of Exhibit 1901 as also your testimony, subject to  
12 the same declaration of truthfulness and correctness  
13 and subject to the same perjury penalty?

14 MR. NICHOLAS: Object to the form of the  
15 question, Your Honor. I believe Dr. Cox's signed  
16 statement incorporates by reference his attachment  
17 there.

18 JUDGE DAVIDSON: Looking at docket stamp page  
19 number 9 or number 10?

20 MR. SPILLER: Docket stamp number -- page 8,  
21 page number 8, Your Honor. At the top line.

22 JUDGE DAVIDSON: Okay. If there's going to be

Corrected as per OR 46 6/13/03

843

1 a disagreement, I've got to look at it.

2 ~~MR. SPILLER~~ <sup>NICHOLAS</sup>: Your Honor, if I could direct  
3 your attention to page 6, line 21?

4 JUDGE DAVIDSON: Let me get to the other one  
5 first, all right?

6 MR. SPILLER: Sorry, Your Honor.

7 JUDGE DAVIDSON: Sorry. It's just -- okay, I  
8 have it. Page 8, I have the one that Mr. Spiller  
9 referred to. Now, there's another declaration?

10 MR. NICHOLAS: No, Your Honor. What I'm  
11 merely pointing out is that on page 6, line 21, it  
12 explains that the attachment is incorporated by  
13 reference, and therefore is subject to the declaration.

14 JUDGE DAVIDSON: Well, I'll still allow his  
15 question, because it's not necessarily that clear.

16 MR. NICHOLAS: Thank you, Your Honor.

17 MR. SPILLER: Now, Dr. Cox --

18 THE WITNESS: Yes.

19 MR. SPILLER: Thank you. Now, in order that  
20 my co-counsel might have a copy to replace that, could  
21 we borrow one of the copies that you now have a  
22 duplicate of Dr. Cox's testimony for Ms. <sup>Steinberg</sup>~~Steinberg~~ to

1 refer to?

2 MR. NICHOLAS: Certainly.

3 BY MR. SPILLER:

4 Q Dr. Cox, if I understand your qualifications  
5 correctly, you are an expert in risk analysis; is that  
6 correct?

7 A Yes, I am.

8 Q Does risk analysis include a number of  
9 subdisciplines, risk communication, the ethics of risk,  
10 risk measurement and risk -- did I say communication?

11 A You did.

12 Q Are those subsets of risk analysis?

13 A Risk analysis has notoriously vague  
14 boundaries. Its traditional definition consists of  
15 three major parts: Risk assessment, which seeks to  
16 rate actions for their probable consequences; risk  
17 management, which seeks to decide what to do once the  
18 risks have been assessed; and risk communication, which  
19 tries to decide what to say about the risks.

20 There are also associated fields that include  
21 risk measurement.

22 Q Thank you. You agree in general that for

1 matters in science, experts in a given field are, in  
2 general, to be accorded more weight than those outside  
3 that field?

4 MR. NICHOLAS: Objection, Your Honor. Calls  
5 for a legal conclusion of the witness.

6 JUDGE DAVIDSON: He can answer.

7 THE WITNESS: I think -- in what context?

8 BY MR. SPILLER:

9 Q For instance, in the context of understanding  
10 scientific testimony, if the scientific testimony were  
11 in the field of risk analysis, would you value it  
12 higher if it comes from a risk analyst than you would  
13 from, say, a lawyer?

14 A I think that's very content dependent.

15 Q So for instance, in your testimony at page 31,  
16 in the two bottom paragraphs on that page, do you have  
17 that page?

18 A Yes, I do.

19 Q When you criticize Dr. Smith and Dr. Angulo  
20 for their epidemiological conclusions, you do that on  
21 the basis of your epidemiological expertise?

22 A I do it on the basis of the content of their

1 statements. So I'm -- I'm not following your boundary,  
2 I guess, between different flavors of relevant  
3 expertise. I'm just looking at the statements and  
4 saying, are they correct according to principles that  
5 are used in statistics, in epidemiology, in risk  
6 assessment, and so forth.

7 Q Do you have a degree in epidemiology?

8 A No, I don't.

9 Q Microbiology?

10 A Although I do teach courses in epidemiology,  
11 I do not have a degree in microbiology.

12 Q Poultry science?

13 A No.

14 Q On page 35 of your testimony, where you  
15 testify that CVM, CDC and various groups opposed to the  
16 use of animal microbials have long asserted in academic  
17 publications and so on, could you identify the various  
18 groups that you're referring to there?

19 A I can certainly identify some of them.  
20 They're listed as sponsors of an upcoming conference on  
21 anti-microbial risk assessment, and some of those  
22 sponsors, including APUA, are I think well identified

1 as opponents to continued use of animal antibiotics.  
2 Others are less well identified.

3 Q And for the record, would you translate APUA?  
4 That sounds like it might be an acronym.

5 A It is. That's APUA. And let's see, it's the  
6 Alliance for Prudent Use of Antibiotics, I believe.

7 Q So you mentioned "groups," plural. I assume  
8 that there's another that you had in mind in this, as  
9 you describe it, campaign.

10 A Yes. Can you -- I'm not quickly finding the  
11 line. I know there are no line numbers. Can you just  
12 point it out to me?

13 Q I'll give you one. On page 35 of your  
14 testimony, the last five lines.

15 A Thank you. And wouldn't you know it. I was  
16 looking at the other page, 37. Yes, here, I see it.  
17 And various groups opposed to the use of anti-  
18 microbials -- certainly.

19 In addition to APUA, there would be the Keep  
20 Antibiotics Working group. There are some  
21 environmental activist groups that I know are very  
22 interested in this issue. And I can think of names if

1 you'd like. There are some European groups.

2 Q Yes, please. It's good to know who are  
3 members of the campaign, so when you can think of those  
4 let us know.

5 A Okay.

6 Q If no more come to mind now, I'll move along.  
7 Do you recall any more now?

8 A I'm not -- I do recall a few other groups,  
9 yes. But as I say, a good source might be the upcoming  
10 conference where there are a lot of stakeholders on  
11 both sides.

12 Q You mentioned some environmental groups. By  
13 name, do you recall those?

14 A I think Environmental Defense is one. If  
15 you're asking for a comprehensive list of those who'd  
16 go on record as being opposed to the continued use of  
17 animal drugs, I can't give you a comprehensive list.

18 Q Only those that you recall now.

19 A Okay.

20 Q And in the next sentence, you mention that  
21 this campaign has established as conventional wisdom  
22 the belief that chickens are the main source or

Corrected as per OR 46 6/13/03

849

1 certainly one of the most important sources of human  
2 CP. I assume you mean campylobacteriosis?

3 A Yes.

4 Q And am I correct that your testimony is to the  
5 effect that your wisdom is different than that  
6 conventional wisdom and yours is the correct one?

7 A I wouldn't put it that way.

8 Q Perhaps I misunderstood. Do you share then  
9 this conventional wisdom?

10 A That chickens are one of the main source or  
11 certainly one of the most important sources of human  
12 campylobacteriosis?

13 Q Yes.

14 A I do not.

15 Q And between your view and the conventional  
16 wisdom today, what is your testimony is the correct  
17 wisdom?

18 A I think they address slightly different  
19 issues. I think the conventional wisdom that you refer  
20 to is based almost entirely on the analysis of  
21 associations, statistical associations, between  
22 ~~checking~~ <sup>chicken</sup> consumption and campylobacteriosis. I believe

Corrected as per OR 46 6/13/03

850

1 that my view and the view of an increasing number of  
2 researchers -- but still a small minority -- is that  
3 that statistical association does not correspond to  
4 causation.

5 As an expert in risk assessment, my primary  
6 interest is in probable consequences of actions; hence,  
7 I focus on the causal question.

8 Q And may I summarize that as you're right and  
9 they're wrong?

10 A No, you may not. You may summarize it as they  
11 have spread a very widely shared perception about  
12 sources, meaning statistical associations, and I  
13 represent a small but growing minority who look beyond  
14 the associations to say, what are the causes of the  
15 ~~associations.~~ <sup>associations?</sup> There's a distinction.

16 Q And you have, I read in your Exhibit B-1573 on  
17 page 3 --

18 A I don't know the numbers.

19 Q All right. I'll have to get that to you.

20 I'm handing you now Exhibit B-1573. Tell me  
21 if you recognize that.

22 A Oh, yes. It is a bio --

1 MR. SPILLER: I'm sorry. Your Honor, may I  
2 hand you one?

3 JUDGE DAVIDSON: Yeah, because I don't seem to  
4 have it, either.

5 MR. SPILLER: I apologize. I believe it is in  
6 the record.

7 THE WITNESS: I recognize it as being a bio of  
8 mine, apparently from about a year ago.

9 BY MR. SPILLER:

10 Q Well, it's referred to in your testimony of  
11 December the 13th of 2002; am I correct?

12 A As I say, this appears to be a bio from about  
13 a year ago. It appears to be the one referred to.

14 Q And in that bio, on page 3 of Exhibit B-1573,  
15 you mention the degree that you just referred to. You  
16 have a Ph.D. in risk analysis from MIT.

17 A Yes, I do.

18 Q But MIT doesn't list you as really having a  
19 Ph.D. degree in risk analysis, does it?

20 A I believe that they do. I have a diploma that  
21 says "risk analysis" on it.

22 MR. SPILLER: Your Honor, I believe our next

1 number to use for marking an exhibit is G-1806. I mark  
2 this as G-1806.

3 (Government Exhibit 1806 was  
4 marked for identification.)

5 MR. SPILLER: On counsel's copy, it will just  
6 be written in ink.

7 BY MR. SPILLER:

8 Q Take a look at this. I'll ask you about it in  
9 a moment.

10 A Um-hmm.

11 Q Dr. Cox, the document that I just handed you  
12 that's labeled G-1806, do you recognize the logo and  
13 the letterhead?

14 A Well, this is MIT.

15 Q Is that the institution you attended?

16 A Yes, indeed, it is.

17 Q And are the dates of attendance reflected  
18 there the dates that you attended MIT?

19 A That looks right.

20 Q And does it bear the signature of a person  
21 saying that it's the facsimile signature of the  
22 registrar in the lower right-hand corner?

Corrected as per OR 46 6/13/03

853

1           A     It has a Mary R. Callahan, it looks like a  
2 stamp to me, yes.

3           Q     And for your masters of science in operations  
4 research, it identifies that degree by specific name,  
5 doesn't it?

6           A     Yes.

7           Q     And for your Ph.D., it says electrical  
8 engineering and computer science as the department,  
9 right?

10          A     As the department, yes, <sup>course</sup> ~~core~~ six.

11          Q     And does not indicate risk analysis, is that  
12 right?

13          A     Not on here, that's correct.

14          Q     Likewise, your bachelor of arts from Harvard  
15 that you mention in your description as being -- and  
16 I'm looking at B-1573, page 3, it says AB in  
17 "mathematical economics," right?

18          A     Specializing in mathematical economics. It's  
19 a general studies degree.

20          Q     I'm sorry. I don't see the words  
21 "specializing in." Am I correct that in your CV you  
22 said that your degree was in mathematical economics?

Corrected as per OR 46 6/13/03

854

1 MR. NICHOLAS: Your Honor, the document speaks  
2 for itself.

3 JUDGE DAVIDSON: Yes.

4 BY MR. SPILLER:

5 Q And Dr. Cox?

6 A Well, actually, I'd like to slow you down a  
7 little bit. The word "likewise" suggests that you're  
8 perceiving a pattern of discrepancies where I believe  
9 that none ~~exist~~<sup>exists</sup>. If you check with MIT a little more  
10 thoroughly, you will find out that I do have a Ph.D.  
11 from the department of electrical engineering, but in  
12 risk analysis.

13 If you check a little more deeply with Harvard  
14 University, you'll find out that I do have an A.B. in  
15 general studies, but that economics was my specialty  
16 and mathematical economics within that field.

17 Q And your degree at Harvard was actually in  
18 economics, wasn't it?

19 A Well, it was from the department of economics,  
20 but it would have been an A.B.

21 Q And if we consulted at Harvard with their  
22 registrar's office, and if we had been referred to the

1 Harvard general counsel's office, do you agree that  
2 they would have said that your degree --

3 MR. NICHOLAS: Objection, Your Honor. Counsel  
4 assuming facts not in evidence.

5 JUDGE DAVIDSON: Let him finish the question,  
6 then you can object.

7 MR. SPILLER: I will withdraw the question,  
8 Your Honor, and borrow an exhibit sticker.

9 I apologize, Your Honor. May I have a moment?

10 JUDGE DAVIDSON: Certainly.

11 (Government Exhibit 1807 was  
12 marked for identification.)

13 MR. SPILLER: I'm passing the witness what's  
14 been marked and not yet in evidence, Exhibit G-1807.

15 BY MR. SPILLER:

16 Q Dr. Cox, do you recognize the letterhead there  
17 as the Harvard University that you attended?

18 A Indeed, I do.

19 Q And am I correct that the representative of  
20 the university's office of the general counsel  
21 indicates that you received your undergraduate degree,  
22 an A.B. in economics, in 1979?

Corrected as per OR 46 6/13/03

856

1 A Yes, although --

2 MR. NICHOLAS: Your Honor, I'm going to object  
3 to this. We don't know who -- whether this has been  
4 signed. This has not been apparently signed by  
5 anybody.

6 JUDGE DAVIDSON: Unfortunately, your witness  
7 has already answered yes. Let him explain, and I'll  
8 listen to the explanation.

9 THE WITNESS: Thank you. Yes, but I believe  
10 there are at least two errors on this. One is, I'm  
11 pretty sure that I was class of 1978.

12 What happened is I went through in three years  
13 instead of four, and I wasn't originally expecting to  
14 do that. I believe the class was '78, and I believe  
15 that my degree is in general studies, although my  
16 concentration was certainly in economics and  
17 specifically mathematic economics. So what you're  
18 showing me, I ~~rush~~<sup>blush</sup> to say, is news to me, although not  
19 necessarily bad news. But I was working full time in  
20 1979.

21 So anyway, you're showing me news and if you  
22 have some question about it, do ask. But especially my

1 Ph.D. degree, I'm rather proud of it and it is --

2 BY MR. SPILLER:

3 Q You mention, Dr. Cox, in Exhibit B-1573, on  
4 page 11 -- let me know when you have the page.

5 A I'm there.

6 Q Under awards and honors, you have five awards  
7 there or honors. Two of them are elected full member  
8 of the Operations Research Society of America.

9 A That's right.

10 Q And the other, elected full member of the  
11 American Statistical Association. And you have  
12 translated a part of what that means up above, under  
13 professional societies for each of them.

14 A Um-hmm.

15 Q You transcribe -- translate full membership.

16 A Yes.

17 Q But you weren't actually elected full member  
18 of ASA, were you?

19 A I certainly was.

20 JUDGE DAVIDSON: Need some more time,  
21 Mr. Spiller?

22 MR. SPILLER: Yes, I apologize, Your Honor.

1 BY MR. SPILLER:

2 Q Dr. Cox, isn't it a fact that one becomes a  
3 full member of the ASA by sending in a completed  
4 application form and \$85?

5 A It is certainly not; that's for general  
6 membership. Unless they've changed the rules. I was  
7 invited, in 1992, as a recognition of my contributions  
8 to the field.

9 Q And so if the ASA membership application form  
10 lists "full member" and includes one year's  
11 subscription and shows \$85, you'd say that's wrong?

12 MR. NICHOLAS: I'm going to object, Your  
13 Honor. This assumes facts not in evidence. The  
14 question assumes facts not in evidence.

15 JUDGE DAVIDSON: I don't know. It's  
16 preliminary to something.

17 THE WITNESS: Would you like me to explain how  
18 the ASA works?

19 MR. SPILLER: I've found the document I need  
20 to label now.

21 (Government Exhibit 1808 was  
22 marked for identification.)

1 MR. SPILLER: I'm handing the witness what has  
2 been marked and is not yet in evidence as G-1808.

3 MR. NICHOLAS: Your Honor, I request the  
4 opportunity to look at this before the witness is asked  
5 that question.

6 MR. SPILLER: I'm now handing a copy to  
7 counsel.

8 JUDGE DAVIDSON: Are you giving copies of  
9 these to the reporter, Mr. Spiller?

10 MR. SPILLER: Yes, Your Honor.

11 JUDGE DAVIDSON: Okay, thank you.

12 Have you had a chance to look at it yet, Mr.  
13 Nicholas?

14 MR. NICHOLAS: I have, Your Honor.

15 JUDGE DAVIDSON: You may ask the next  
16 question.

17 BY MR. SPILLER:

18 Q Dr. Cox, looking at what's been marked G-1808,  
19 from whom does that purport to be?

20 A From Bill Smith.

21 Q And how is his name described at the bottom  
22 and what is the title?

1           A     William B. Smith, Executive Director, American  
2     Statistical Association. Dated May 2003.

3           Q     And does he indicate any membership category  
4     such as full elected member or elected full member?

5           A     Not in 2003, no.

6           Q     And does he use the term such as "only" to  
7     describe a complete list of the categories of  
8     membership in that organization?

9           A     Not in 2003.

10          Q     Without another document, Dr. Cox, would you  
11     agree that in forms, the Institute for Operations  
12     Research and Management Sciences would similarly say  
13     that your class of membership there is regular?

14          A     I may have -- I may have let my dues lapse.  
15     It may not be down to regular. For the statistical  
16     association, I was sponsored by Hunter, who is an  
17     eminent statistician. I remember getting the  
18     invitation. So although I see what you're talking  
19     about here, I can tell you back in 1992, it was a bit  
20     different.

21          Q     And is it your testimony here today that you  
22     were elected in 1992 to full membership in the American

1 Statistical Association?

2 A That is my understanding. I was invited based  
3 upon nomination and election, according to the letter  
4 that I received, yes. And as I say, Professor Hunter  
5 was my sponsor, as I recall, if you wish to verify.

6 Q Thank you, Dr. Cox.

7 You did work in causal inference some years  
8 ago, at least as far back as 1995, am I correct?

9 A Oh, yes.

10 Q So you would have been aware of the  
11 appropriate use of causal inference well before 1999,  
12 am I correct?

13 A Certainly.

14 Q Is it fair to say that your testimony, taken  
15 as a whole, expresses disagreement and disapproval of  
16 the FDA risk assessment in this record, that's  
17 Government Exhibit G-953? Are you familiar with the  
18 FDA risk assessment for campylobacter in chicken?

19 A Yes, I am.

20 Q And is it fair to take your testimony as  
21 expressing disagreement, disapproval with that?

22 A Do you mean disagreement with its conclusion?

1 Or disapproval with its conclusions or its approach?

2 Q Let's take those in turn. Do you disagree  
3 with its conclusion?

4 MR. NICHOLAS: Your Honor, if the witness  
5 could be provided with a copy of the document counsel  
6 is referencing?

7 JUDGE DAVIDSON: Of course.

8 And feel free to ask for that if other  
9 questions come up referring to documents you don't have  
10 in front of you.

11 THE WITNESS: Thank you.

12 JUDGE DAVIDSON: We don't want you to have to  
13 do everything from memory.

14 THE WITNESS: I appreciate that. Thank you.

15 BY MR. SPILLER:

16 Q Dr. Cox, I'm handing you now what is in  
17 evidence as Exhibit G-953.

18 A Thank you.

19 Q And if I may, I'll remove these items of  
20 correspondence. I don't plan to ask you further  
21 questions about these.

22 A Okay.

1 Q While you're looking at that --

2 MR. SPILLER: Your Honor, I did not move and I  
3 do now move Exhibits G-1806 from MIT, G-1807 from  
4 Harvard, and G-1808 from the American Statistical  
5 Association, in evidence.

6 JUDGE DAVIDSON: No, I'm not going to receive  
7 them at this point. I will allow receipt -- Dr. Cox  
8 has given an explanation for most of your questions and  
9 apparent discrepancies that you allegedly found. I  
10 will allow, however, if you remind me -- both sides --  
11 at the conclusion, a short opportunity for filing  
12 documents to support one way or another, if you think  
13 it's important. It will be very short and will be  
14 limited to alleged discrepancies in witnesses'  
15 testimony or cross-examination. It won't involve -- I  
16 don't want to see any more exhibits or new things. All  
17 right?

18 So I'm not going to receive that in evidence  
19 as of now. I may subsequently receive it in evidence,  
20 if the material you provide me shows that there was, in  
21 fact, material discrepancy.

22 All right?

1 BY MR. SPILLER:

2 Q Dr. Cox, I think the question we were working  
3 on was whether or not it's fair to interpret your  
4 written direct testimony, that's Exhibit B-1901, as  
5 expressing your disagreement with the FDA risk  
6 assessment in this matter, which is Exhibit G-953.

7 A I think it will be most useful to talk  
8 specifics. There are things in that that I disagree  
9 with. There are important things in it that I disagree  
10 with. But I don't disagree with every sentence in it.

11 Q Let's begin that discussion with an answer to  
12 my question. In general --

13 A Is it fair? I don't think so.

14 Q Do you agree with its conclusions?

15 A Which ones?

16 Q The conclusion of the number of persons  
17 estimated to have suffered from campylobacteriosis  
18 attributable to chicken consumption in the United  
19 States for the years 1998 to 1999, who were treated  
20 with a fluoroquinolone?

21 MR. NICHOLAS: Your Honor, if counsel could  
22 point to the exhibit and show the witness what he's

1 referring to, it might --

2 BY MR. SPILLER:

3 Q Dr. Cox, was my question not clear to you?

4 A I wouldn't -- I don't think it addressed  
5 suffering. But if you mean the 10,000 to 15,000  
6 conclusion, roughly speaking, I do believe that that's  
7 inaccurate as interpreted by CVM.

8 Q And do you disagree with its methods, as well?

9 A Yes, I do. And models.

10 Q But in May of 1999, you agreed with CVM's risk  
11 assessment, didn't you?

12 A Agreed about what?

13 Q You agreed that its statistical and risk  
14 assessment methodology was appropriate?

15 A I think we have to be careful here. I was  
16 asked, first by David and then by CVM, to review the  
17 methodology. In April of '99, I sent a many-paged  
18 letter to David before understanding the problem very  
19 well.

20 Q Would you identify David for the record,  
21 please?

22 A My colleague, David Vose. Sorry.

1 Q Thank you.

2 A I sent him a fairly detailed letter suggesting  
3 how one might tackle the approach. I believe that what  
4 I said on the CVM website and at CVM is that the  
5 approach seemed to me, a priori, to be sensible. The  
6 assumptions seemed to me to be well-documented. That  
7 generally I liked the approach, but I felt it was very  
8 important to validate it before using it for any  
9 purpose and before accepting it.

10 MR. SPILLER: I'm just marking, Your Honor, an  
11 exhibit not yet in evidence.

12 (Government Exhibit 1809 was  
13 marked for identification.)

14 BY MR. SPILLER:

15 Q Dr. Cox, you mentioned that you had engaged in  
16 correspondence in April of 1999. I hand you now what's  
17 been marked G-1809 and ask you if that reflects the  
18 correspondence to which you referred.

19 A I was thinking of something a little earlier,  
20 but this is from the same era. Are we still talking  
21 about a Product Y here?

22 Q In your consulting work, does it sometimes

Corrected as per OR 46 6/13/02

867

1 happen that as you design risk analyses, you discuss  
2 products in the abstract or by code name to avoid  
3 identifying products and manufacturers.

4 A It sounds plausible to me. I don't know that  
5 I've seen that before, but yes.

6 Q Do some of your clients like to be held  
7 confidential?

8 A Surely. And this does contain -- this does  
9 contain the thought <sup>piece</sup> ~~keys~~ that I was thinking of. Let  
10 me just clarify, this was before I knew what the  
11 problem was that we were looking at.

12 Q And when you evaluated this approach of David  
13 Vose's, am I correct that the data analysis elements  
14 that are described in your summary on page 1 of 10 are  
15 data elements that -- sometimes not bearing the same  
16 variable name, are nonetheless incorporated in FDA's  
17 risk assessment?

18 A I'm sorry. Would you please ask the same  
19 question again?

20 Q Aren't those same data analysis elements also  
21 in FDA's risk assessment, Exhibit G-953?

22 A No. If you look at number 3, the potency

1 parameter and also the number of episodes are not  
2 reflected. There certainly is a big K. But -- those  
3 parameters are not reflected in the risk assessment.  
4 The joint frequency distribution of type K cases per  
5 episode -- the joint frequency distribution is  
6 certainly not reflected.

7           Were you limiting your question to just the  
8 data analysis elements on page 1 here?

9           Q    No, and I think we can also ask about the  
10 conclusions you have on that page. Beneath the text  
11 box on page 1 of 10 of what's been marked G-1809, you  
12 have a two-sentence conclusion. Am I correct, you  
13 concluded: This seems to me to be a very practical and  
14 technically sound approach; I have no remaining  
15 concerns.

16           A    With emphasis on "seems" and in the context of  
17 April, this seemed like a good approach to the problem  
18 David had described. Which I would distinguish from  
19 the problem that CVM was undertaking to solve.

20                    Completing my answer to your former question  
21 about data elements, and bearing in mind that you said  
22 you were not referring or limiting your question only

Corrected as per OR 46 6/13/03

869

1 to page 1, I would refer you also to page 3 of 10,  
2 paragraph marked paragraph 2. Moreover, probability --  
3 my response, Q2, "yet the probability that exactly one  
4 person will become ill may be less than the probably  
5 that two or more will become ill, right?" That data  
6 element, and in fact information related to dose  
7 response information for individuals or for small  
8 groups or for families or for clusters as highlighted  
9 in bold, close to the bottom of the page -- those  
10 parameters have not been captured in the current model  
11 and numerous other parameters have not been captured in  
12 the current model.

13           Completing my answer to your question two,  
14 yes, I did say, <sup>"this</sup> ~~this~~ seems to me to be a very practical,  
15 sound approach. I have no remaining concern." I want  
16 to clarify again the context for that was the problem  
17 as described to me by my colleague, David Vose, not the  
18 problem that I have referred to in the context of the  
19 CVM risk assessment.

20           Q     And from your knowledge of epidemiology,  
21 referring to page 3 of 10 as you just did, the fourth  
22 line from the bottom of the page, the bolded term,

1 clusters of cases, in epidemiology, a cluster of cases  
2 is called an outbreak, isn't it?

3 A Not necessarily. They can be spacial  
4 clusters. An outbreak is more likely to be a temporal  
5 cluster. Let me just say, not necessarily.

6 Q And so in your note Q2, the probability of  
7 more people becoming ill would describe the mechanism  
8 of an outbreak, would it not?

9 A Yes. If a chicken is contaminated, it could  
10 be for an outbreak. Or, in the current context, it  
11 could be that, I mean, often only the first person in  
12 the family who gets campylobacteriosis is recorded, and  
13 it's not recorded as an outbreak; it's recorded as a  
14 sporadic case. So I think we need to be a little bit  
15 careful with that term "outbreak."

16 Q And from your knowledge of the epidemiology of  
17 campylobacteriosis outbreaks, you know that they are  
18 the minority of the cases of human campylobacteriosis  
19 in developed countries, don't you?

20 A Yes, based on reported data. Again, but the  
21 caution on the exact meaning of "outbreak." For  
22 example, if several people in the same family get sick,

1 ~~it's~~ <sup>is it</sup> an outbreak?

2 Q You conditioned that based on reported data.  
3 You're not suggesting that we should base things on  
4 other than reported data, are you?

5 A Oh, sure, there's lots of data I'd like to  
6 have, including data on multiple incidents within one  
7 family or multiple people in the same restaurant.

8 Q So that was your professional opinion to Dr.  
9 Vose in April of 1999. And for your professional  
10 opinion, you billed him and he paid, right?

11 A Yes. Well, I think he didn't really pay me  
12 for the opinion so much as for the analysis, the  
13 reasoning.

14 As you can see from the tone, this is  
15 colleagues chatting about an interesting hypothetical  
16 problem.

17 Q And one of those colleagues took home over  
18 \$1000 for it, right?

19 A Probably.

20 Q And in December of 1999, did you attend at  
21 FDA's invitation and expense a public meeting to  
22 evaluate the FDA risk assessment?

1 A That sounds right, yes.

2 Q And that's when you did the PowerPoint slide  
3 presentation that you mentioned earlier?

4 A On FDA's website. I would have done it  
5 shortly before then but, yes.

6 Q And at that time, you said, am I correct, it's  
7 a pretty good approach, pretty sensible study, it hangs  
8 together?

9 MR. NICHOLAS: Your Honor, if counsel would  
10 provide the witness with copies of the documents?

11 THE WITNESS: Thanks. But I do recognize  
12 those remarks as being my opinion at the time. It was,  
13 a priori, a pretty reasonable approach.

14 BY MR. SPILLER:

15 Q Thank you. I think, if I can express them  
16 fairly, that will save us time and a document. I think  
17 you will recognize these. "All in all, I think it's a  
18 job well done"?

19 MR. NICHOLAS: Your Honor, the document speaks  
20 for itself.

21 JUDGE DAVIDSON: If he doesn't want to answer  
22 it, if he doesn't remember, he can say so.

1 THE WITNESS: Would you read the quote back  
2 again, please?

3 BY MR. SPILLER:

4 Q Yes. "All in all, I think it is a job well  
5 done."

6 A And your question?

7 Q Do you remember saying words to that effect to  
8 the conference to evaluate CVM's risk assessment on  
9 December 9, 1999?

10 A Yes. But let me clarify. I said that about  
11 the job that David had done responding to their  
12 request. So I thought he had done a good job of  
13 documenting assumptions. I thought that the model was  
14 fairly explicit. I had not at that time acquainted  
15 myself with the data or validity of the model.

16 Q Dr. Cox, I hand you now what's been marked  
17 Government Exhibit 1810, not yet in evidence. Here's a  
18 copy for the Court. A copy for Madam Reporter. A copy  
19 for counsel.

20 (Government Exhibit 1810 was  
21 marked for identification.)

22 MR. SPILLER: I will not ask questions about

1 it until counsel signals his readiness.

2 I would like to note for the record that this  
3 is the first day of the transcript that -- the second  
4 day has already been admitted in this docket, at the  
5 behest of AHI, as Exhibit A, like alpha, 121.

6 THE WITNESS: Okay.

7 MR. SPILLER: I'm sorry, Dr. Cox. There's no  
8 question. We're waiting until your counsel is ready.

9 THE WITNESS: While we're waiting, would it be  
10 okay --

11 JUDGE DAVIDSON: There's nothing pending. The  
12 record will reflect everything that you say, so let's  
13 not assume. If you want to explain an answer, feel  
14 free to do so.

15 THE WITNESS: That's just it, Your Honor.

16 JUDGE DAVIDSON: -- previous question?

17 THE WITNESS: Previous question.

18 JUDGE DAVIDSON: Your explanations are quite  
19 long to start with.

20 THE WITNESS: I felt that there was a quote  
21 out of context. And I happened to turn to the exact  
22 context, and I wondered whether it would be useful to

1 read.

2 JUDGE DAVIDSON: Well, if it's here, we will  
3 get to that. If it doesn't --

4 THE WITNESS: Okay, thank you.

5 MR. NICHOLAS: Your Honor, if I could take one  
6 more minute to look at this?

7 JUDGE DAVIDSON: Certainly.

8 MR. NICHOLAS: Thank you.

9 I'm ready, Your Honor. Thank you.

10 BY MR. SPILLER:

11 Q Dr. Cox, I know you wanted to complete an  
12 earlier answer of a question. And whenever I ask you  
13 to look at a quote, I intend for you to look at  
14 context. So fill us in on the context that you just  
15 described, please.

16 A Thank you. It's on page 141.

17 JUDGE DAVIDSON: Of this exhibit?

18 THE WITNESS: Of this exhibit, G-1810, that I  
19 was just handed. The page number is in the upper  
20 right-hand corner. It's the page on which the first  
21 complete sentence is, I mean -- like 10, it -- the  
22 study, the model -- it has to make a few baroque

1 assumptions, K being the big one, to get across big  
2 data gaps, but it is very explicit about that. So all  
3 in all, I think that is a job well done. I want to  
4 invite you to critically examine a few assumptions if  
5 you share that conclusion.

6 So it is contingent on the validity of that  
7 big K.

8 MR. SPILLER: Thank you, Dr. Cox.

9 THE WITNESS: You're welcome.

10 MR. SPILLER: Your Honor, I can avoid a number  
11 of other questions with a motion to admit in evidence  
12 G-1810. So then Dr. Cox, I can avoid asking you did  
13 you say or didn't you say.

14 JUDGE DAVIDSON: Mr. Nicholas?

15 MR. NICHOLAS: Your Honor, given the fact that  
16 Mr. Spiller was interested in the context in which  
17 these statements were made, I would prefer to have him  
18 address the questions explicitly to the witness and  
19 have that opportunity.

20 JUDGE DAVIDSON: I know what you prefer, but  
21 are you objecting to the admission of this document  
22 into evidence?

1 MR. NICHOLAS: No, I am not, Your Honor.

2 JUDGE DAVIDSON: Okay, it's in evidence.

3 (Government Exhibit 1810 was  
4 received in evidence.)

5 MR. SPILLER: Thank you, Your Honor.

6 BY MR. SPILLER:

7 Q Dr. Cox, one summarizing comment, and I think  
8 I can move on. On page 140 of Exhibit G-1810, lines 18  
9 to 24?

10 A Yes.

11 Q I've mis-cited you. Sorry.

12 MR. SPILLER: Your Honor, may I have a moment?

13 JUDGE DAVIDSON: Certainly.

14 BY MR. SPILLER:

15 Q On page 143, Dr. Cox, lines 15 through 21, am  
16 I correct that you are agreeing there explicitly with  
17 the model's incorporation of the aggregation of end  
18 sequences into one large probability? Is that what you  
19 called a "big K"?

20 A Yeah. Big K in this model -- the model says  
21 risk is equal to big K exposure. That was my simple  
22 statement of the model. And big K, also called K RES,

0  
Corrected as per OR 46 6/13/03

878

1 K sub RES when we're talking about resistant  
2 campylobacteriosis, K with no subscripts when we're  
3 talking about ordinary campylobacteriosis, that is the  
4 big K that I'm talking about.

5 Q And so without reading you the text, on 144,  
6 lines 3 through 8 --

7 A Wait a minute, I'm sorry. Were we finished?  
8 Did I answer your question about 143?

9 JUDGE DAVIDSON: I thought you did.

10 BY MR. SPILLER:

11 Q Yes, in general. Never mind. I'll ask a  
12 question.

13 And so that's consistent with what you say on  
14 144, lines 3 through 8, about modeling the product to  
15 put the number of things together, right?

16 A Yes, again, in the context of given David's  
17 assumptions and what he was trying to do. I talk about  
18 big or wholesale validation, where you try to say, <sup>"Is</sup> ~~is~~  
19 this model correct and useful?" And then I talk about  
20 little validation, <sup>"Do</sup> ~~do~~ saying, <sup>"</sup> its consequences follow  
21 from its premises, <sup>"</sup> so is it logically valid, even if  
22 it's not necessarily empirically valid? So these

1 comments are directed at a logical matter, if you would  
2 make the big K model work, a lot of little factors,  
3 that would be a terrific thing to do.

4 Q And the risk assessment itself, referring to  
5 what is now G-953, didn't change much between then and  
6 now, did it, Dr. Cox?

7 A On that, a somewhat imponderable question.  
8 The big K principle has been carried through ever  
9 since. I now see it as a real disaster.

10 Q That's the summary I was looking for earlier.

11 A You got it.

12 Q In the risk assessment, am I correct that the  
13 changes are collected and are summarized and they  
14 reflect -- excuse me, let me give you the cite. If you  
15 would look in Exhibit G-953?

16 A Yes. I have it here.

17 Q At page 25. Those are the changes that were  
18 made between the December draft to which you addressed  
19 the comments that we just described and the final  
20 version which is now this exhibit, right?

21 A I will assume so. There are things like the  
22 days in calculation and an appendix that I'm not sure

Corrected as per OR 46 6/13/03

880

1 are captured here. But let's go with that. It looks  
2 pretty plausible.

3 Q One of your key criticisms, your first  
4 criticism in your detailed testimony -- I'm now  
5 referring to your testimony B-1901 at page 9 --

6 A Yes.

7 Q -- was that the CVM model follows a  
8 nontraditional risk assessment methodology that yields  
9 invalid conclusions about human health risks, right?

10 A Yes.

11 Q At the time of your 1999 review that we just  
12 discussed with CVM, you were aware of how human health  
13 risks assessments should be carried out? ~~Question~~

14 A Pause. Yes, I was aware of how to do human  
15 health risk assessment generally. I had not yet  
16 studied this field, as I have now.

17 Q In fact, this is the first microbial or  
18 antimicrobial risk analysis you've ever done, right?

19 A Well, there was one with <sup>Virginia mycili</sup> ~~Virginia Misen~~ that  
20 I've also done. But this was certainly one of the  
21 first.

22 Q If it's not the first, it's the second?

1           A     Well, it's less than tenth, I'm sure. I've  
2 also looked at a couple of other -- oh, you said anti-  
3 microbial risk assessment, and here I was thinking of  
4 microbial risk assessment.

5           A     So yes, I think this is the first time I  
6 looked at anti-microbial risk assessment.

7           Q     So you were aware of how human health risk  
8 assessments were done then. And yet you didn't raise  
9 that allegation that they didn't follow traditional  
10 risk assessments at the time, did you?

11          A     It didn't seem relevant. Back then, it was an  
12 exciting and innovative method.

13          Q     Well, as to how it's become relevant, Dr. Cox,  
14 when did you first work for AHI on --

15          A     I resist the implication.

16          Q     And would you answer the question, anyway,  
17 please?

18          A     John Keeling at AHI first approached me soon  
19 after that public meeting. And I don't remember the  
20 chronology of when exactly I started work for them in  
21 terms of billable work, but it would have been soon  
22 after this public meeting.

1 Q I forgot to ask you, at the public meeting,  
2 FDA paid for your travel and per diem to that meeting,  
3 right?

4 MR. NICHOLAS: Asked and answered, Your Honor.

5 JUDGE DAVIDSON: It was a previous -- the  
6 question dealing with his payment from FDA was for Dr.  
7 Gross, for the original. But if I'm wrong, we will let  
8 him answer it again.

9 MR. NICHOLAS: Thank you, Your Honor.

10 BY MR. SPILLER:

11 Q Do you recall the question?

12 A Yes. And it was if the FDA paid me a per diem  
13 and expenses. Yes, they did.

14 JUDGE DAVIDSON: That's for the meeting, the  
15 transcript in 1810?

16 THE WITNESS: Yes, Your Honor. Yes.

17 BY MR. SPILLER:

18 Q And that covered your consultancy time that  
19 you necessarily expended to assemble the PowerPoint  
20 presentation that you described?

21 A It covered partly, yes.

22 Q And you gave us the discounted rate.

0  
Corrected as per OR 46 6/13/03

883

1 A Right.

2 Q Did you give AHI a discounted rate?

3 A Initially, I did, yes.

4 Q And so your work for AHI continued for some  
5 time, past the discounted rate into the full rate  
6 period?

7 A Yes, it did.

8 Q And that continues to this day?

9 A To this hour.

10 Q And have you independently or separately also  
11 worked for Bayer during any of that time?

12 A I don't believe so.

13 Q Without getting into any unseemly details, is  
14 it fair to say that AHI has required more of your time  
15 and therefore has paid for more of your time than the  
16 government ever did on this project?

17 A Yes. Well, "required" may be too strong. AHI  
18 asked me for a bid on what I thought it would take to  
19 develop a sound approach to risk modeling, and I gave  
20 them that bid. And that refers to <sup>~</sup>~~the~~ number of  
21 contracts. So it was a negotiated and repetitious  
22 arrangement, rather than a requirement of time.

1 Q And you did work up an assessment for AHI, am  
2 I correct?

3 A Several, yes.

4 Q One of which you mentioned, I think in your  
5 testimony, had been submitted for publication in the  
6 International Journal of Infectious Diseases?

7 A Yes, that's correct.

8 Q And was there anything unusual about that  
9 particular issue of the International Journal of  
10 Infectious diseases?

11 A Yes, there was.

12 Q And among the things that were unusual was  
13 that issue devoted to the therapeutic use of  
14 Fluoroquinolone in poultry, the effect on  
15 campylobacter, and the potential to human health  
16 consequences? That was the topic of that supplement?

17 A Yes.

18 MR. NICHOLAS: Your Honor, if the witness  
19 could be provided the document as well, and so obtain  
20 his answers to the questions?

21 JUDGE DAVIDSON: He can ask for it, and you  
22 should provide it if you're going to ask any detailed

1 questions about the document.

2 (Government Exhibit 1811 was  
3 marked for identification.)

4 MR. SPILLER: Your Honor, I'm handing the  
5 witness what has been marked and is not yet in evidence  
6 as Exhibit G-1811. One for the Court, one for the  
7 reporter, one for counsel.

8 I won't ask you any questions about it until  
9 counsel signals that they've had a chance to look at  
10 it.

11 BY MR. SPILLER:

12 Q Dr. Cox, is this a publication of a paper that  
13 you developed while working for AHI?

14 A In part, yes.

15 Q And how was the work funded that resulted in  
16 this paper?

17 A I believe that the costs of distributing the  
18 special issue -- actually, this is outside my area of  
19 expertise. I think I know the answer, but it's  
20 something that I'm not an expert on.

21 Q The question that I meant to ask, and I  
22 apologize if I didn't ask it is, how did you get paid

1 for the work you did to write the paper that eventually  
2 went to this journal?

3 A I'm not sure that I did get paid. That paper  
4 was a lot of work. But there was a workshop in  
5 Boston -- I can't remember exactly where it was held,  
6 but there was a workshop in Boston where a bunch of  
7 folks got together to talk about, is there a better way  
8 of doing this. And I participated in that. And then  
9 this was the paper that came out of that workshop.

10 Q And were most of those folks that attended  
11 that conference government folks, or were they folks  
12 working with Bayer and AHI?

13 A I think they were mainly -- I think it was  
14 academic, and --

15 Q You're an academic, aren't you, Dr. Cox?

16 A In part, yes. I know there were some  
17 academics. And there were some industry folks. There  
18 were people like Diane Newell, who I had not previously  
19 met, who I know works for Bayer and is a witness in  
20 this case. And there were not government folks,  
21 although my impression was they wanted to have them  
22 there. But again, I didn't organize the meeting. It's

1 really outside my expertise.

2 Q And that workshop actually was by invitation  
3 only, wasn't it?

4 A Perhaps. I certainly got an invitation.

5 Q And the fellow authors, referring to the  
6 exhibit before you on its third page, which is numbered  
7 only in the upper right-hand corner with a fax  
8 transmittal number, 004, five of those seven  
9 contributing authors are witnesses either for AHI and  
10 Bayer in this matter, aren't they?

11 A Is that right?

12 Q And there was a statement by Ginivan, who's  
13 not a witness here, that was attached to Dr. Carnival's  
14 testimony here, wasn't it?

15 A I believe so, yes.

16 Q And the last two lines on the page indicate  
17 that the publication of the supplement is aided by an  
18 unrestricted grant from Bayer Healthcare. What's your  
19 understanding of how that grant was applied and  
20 distributed?

21 MR. NICHOLAS: Object, Your Honor. The  
22 witness --

1 THE WITNESS: It's outside my area of  
2 expertise. I think --

3 JUDGE DAVIDSON: He'll answer if he knows. He  
4 doesn't.

5 BY MR. SPILLER:

6 Q Do you know what a vanity journal is, Dr. Cox?

7 A Yes, I do.

8 Q Is that what this was?

9 A I've -- I don't know. It's not in deadline, I  
10 can tell you that. I don't think it was. And again, I  
11 tend to have some area of expertise. I think Bayer  
12 helped to -- Bayer, with some of the production costs.

13 MR. NICHOLAS: I object. The witness already  
14 testified. It's outside --

15 JUDGE DAVIDSON: You're interrupting your own  
16 witness. You can move to have it stricken if you don't  
17 want his answer on the record, but let him finish.

18 THE WITNESS: Well, the point is we wrote the  
19 stuff independently and sent it in for legitimate  
20 review. And I don't know what happened from there.

21 BY MR. SPILLER:

22 Q Was it reviewed by the regular review panel of

1 the International Journal of Infectious Diseases? Or  
2 was it reviewed by the guest editors that are  
3 identified there?

4 A I am not clear on what the review process was.

5 Q Do you know if they turned down any papers  
6 submitted by Bayer or AHI witnesses?

7 A I don't know. I know that we did get some  
8 reviewer comments back.

9 Q Turning back to your testimony, Dr. Cox, and  
10 within that page 30, three-zero --

11 A Yes.

12 Q You mentioned -- excuse me, let me find it --  
13 the second bullet begins with the words "by contrast."  
14 Do you see on page 30 the second bullet?

15 A I am looking at it, yes.

16 Q And without clouding the transcript with more  
17 words, I will just let you read that quietly. And then  
18 signal me when you're through, and I'll have a  
19 question.

20 A Okay, ready.

21 Q So the references you mentioned there, your  
22 thorough studying of those references led you to

Corrected as per OR 46 6/13/03

890

1 conclude that they all support your notion that it's  
2 restaurant dining that's the major cause of  
3 campylobacteriosis, rather than chicken consumption; is  
4 that right?

5 A No, that -- there are several refinements  
6 necessary. First, I wouldn't pretend to a thorough  
7 study of these references. And secondly, I think  
8 Eberhart Phillips contains information on both sides of  
9 the question. Also, the -- what I rely on, if I can,  
10 is the data, not the citation.

11 See, if this is consistent with the data of  
12 Effler, et al., 2001, but not necessarily with what  
13 Effler himself concluded from the data using logistic  
14 ~~progression~~ <sup>regression</sup> models and not doing a very thorough job.

15 Q I want to make sure I understand you. When  
16 you say it's consistent with the data, you mean it's  
17 consistent with your interpretation of the data, even  
18 though that may be, in the instant you mentioned,  
19 inconsistent with the author's evaluation of that same  
20 data?

21 A To the extent possible, I would like to remove  
22 "interpretation" and "evaluation" from there, and just

1 address the question is the hypothesis consistent with  
2 the data itself, not with somebody's interpretation of  
3 the data.

4 Q So in the Adak citation -- am I pronouncing  
5 that right?

6 A I don't know. Sounds good to me.

7 Q There's a citation that the author's name is  
8 Adak. It's identified in your testimony as B-122.  
9 Without me tossing you an exhibit --

10 A Oh, please do.

11 Q -- do you recall if restaurant dining is  
12 actually evaluated in that paper?

13 MR. SPILLER: I'm now handing the witness  
14 Exhibit B-122.

15 THE WITNESS: Thank you.

16 MR. SPILLER: I believe it's in the record,  
17 but I have a copy for the Court.

18 BY MR. SPILLER:

19 Q Dr. Cox, would you take the time necessary to  
20 refer me to the part of that article that considers  
21 restaurant dining, apart from chicken, as a risk  
22 factor, please?

Corrected as per OR 46 6/13/02

892

1           A     This is a reference for the "rather-than-  
2           chicken <sup>consumption, per se</sup> ~~assumption, per se~~, portion, not for the  
3           "restaurant dining" portion. So I cannot refer you to  
4           the restaurant dining. This reference doesn't support  
5           that point.

6           Q     So when you put that cite after the italicized  
7           for emphasis text, "thus restaurant dining rather than  
8           chicken consumption, per se," we should not take that  
9           to mean that your reference actually supports your most  
10          recent previous emphasized sentence?

11          A     To the contrary. This is a compound sentence  
12          that entails at least two propositions. One  
13          proposition is that restaurant dining is a risk factor.  
14          The other is that chicken consumption, per se, does not  
15          appear to be such a factor. This reference supports  
16          the second of those two points.

17          Q     Dr. Cox, on page 4 of that reference --

18          A     Um-hmm. Yes, okay.

19          Q     There are a number of references to  
20          consumption of chicken, including one that has an  
21          adjusted odds ratio of 4.65, am I correct?

22          A     Which -- can you point it out to me?

1 Q I'm on page 4, table 2.

2 A Got it.

3 Q The sixth factor down. It's titled,  
4 "Consumption of hot chicken away from home,  
5 undercooked."

6 A Well cooked. Undercooked, cases 9, controls  
7 4. Yes. I'm looking at it. So you're looking at the  
8 odds ratio of 4.65, confidence interval, .95 to 22.8.  
9 Is that what you're referring to?

10 Q I am.

11 A Okay, I see it.

12 Q Does that not support a relationship of  
13 consumption of chicken?

14 A On the face of it, it does not. If I'm  
15 reading it correctly, the confidence interval is from  
16 below 1 to above 1. Also, these are crude odds ratios.  
17 And thirdly, the relation that you're referring to is  
18 not a statistical association, but a causal relation,  
19 then, a fortiori, does not. But even on the face of  
20 it, it doesn't. It isn't a statistical association.

21 Q So following your lead, the consumption of  
22 barbecued chicken, undercooked, showing an odds ratio

Corrected as per OR 46 6/13/03

894

1 of 16, and the confidence intervals, as you pointed  
2 out, are not inclusive of one, and the  $F$  value is less  
3 than .01, would be in this listing significant  
4 association between consumption of chicken --

5 A Ah, good question. And had the T values been  
6 calculated to adjust for multiple testing, it would be  
7 evidence of association. But as you will see, as  
8 within so many studies, we have, I think, over a dozen  
9 factors here each being tested and a few of them  
10 showing up as being significant -- don't be impressed  
11 by big odds ratio because of the logarithm scale that  
12 goes as low as zero but as high as 70.

13 Q And your second reference for that sentence,  
14 Friedman G-228?

15 MR. NICHOLAS: Your Honor, I believe that  
16 sentence has more than two references --

17 JUDGE DAVIDSON: He just said the second  
18 one --

19 THE WITNESS: Okay, Friedman, et al.

20 BY MR. SPILLER:

21 Q You reference that about 13 times in your  
22 testimony, didn't you?

Corrected as per OR 46 6/13/03

895

1 A I love that data <sup>set</sup> ~~step~~.

2 MR. SPILLER: I'm sorry, Your Honor. This is  
3 in the record.

4 BY MR. SPILLER:

5 Q And again, there is no restaurant dining  
6 factor used in this study, is there?

7 MR. NICHOLAS: Your Honor, I would object.  
8 This whole study is in draft form attached to Dr.  
9 ~~Angelo's~~ <sup>Angulo's</sup> testimony. And if the witness is going to be  
10 asked about it, I would request that he be provided a  
11 copy of I think it's Attachment 3 to Dr. ~~Angelo's~~ <sup>Angulo's</sup>  
12 testimony, which I think is G-228. This is an abstract  
13 from the CDC website --

14 JUDGE DAVIDSON: Let's hear what the question  
15 is first. If you've got a problem and he needs to look  
16 at the entire study, then we'll let him look at it.

17 MR. NICHOLAS: Thank you, Your Honor.

18 BY MR. SPILLER:

19 Q Dr. Cox, does your reference tell anybody  
20 anything other than the author's name and the year  
21 here? Can you distinguish from that whether it's this  
22 Friedman, or the Friedman that --

1           A    Oh, this -- I'll just stipulate, it is this  
2 Friedman.

3           Q    Thank you.

4           A    But then your question about restaurant  
5 dining?

6           Q    Am I correct, since you've indicated that this  
7 is the study you're referring to --

8           MR. NICHOLAS: Your Honor, I believe the  
9 witness indicated this is the person, not the study.

10          THE WITNESS: Correct.

11          MR. NICHOLAS: He is not referring to this  
12 particular abstract --

13          JUDGE DAVIDSON: Let's get it straight.

14          THE WITNESS: It's really the data that  
15 matters.

16          BY MR. SPILLER:

17          Q    I want to accommodate your counsel's concern,  
18 and I want to play through some of the difficulties we  
19 have with citations. In the list of references for  
20 your paper, in your written direct testimony at page  
21 89?

22          A    Yes.

1 Q You have two Friedmans, am I right, two  
2 Friedman cites?

3 A Two Friedman cites, yes, I do.

4 Q And both of them are 2000. And one of them  
5 has, according to your cite, a web citation of -- and I  
6 won't recite it all.

7 A Yes.

8 Q And that is the same web citation on G-228,  
9 isn't it?

10 A I believe that it is.

11 Q So this is the one you were citing?

12 A Yes, this is the study and I've analyzed these  
13 data.

14 Q Where in the data reflected in this exhibit is  
15 any consideration of restaurant dining as a risk  
16 factor?

17 A That's really two questions. In the data,  
18 restaurant dining appears for over a dozen variables  
19 that are marked with D, perhaps for dining, at the end  
20 of them. Compared to A, for at home.

21 Where it's reflected in this exhibit, to the  
22 extent that it is, is -- when you say eating chicken or

Corrected as per OR 46 6/13/03

898

1 turkey in the home was a protective factor, eating  
2 chicken or turkey that was cooked outside the home on  
3 the previous page and eating a non-poultry meat that  
4 was cooked outside the home. "Outside the home"  
5 includes restaurant dining. So that would be right  
6 around the middle of this paragraph.

7 Q And in your testimony, you refer to the  
8 findings of these, and you refer to this as an  
9 international study?

10 A Correct.

11 Q So where in the findings do we see restaurant  
12 dining?

13 A The same -- this is very much like your  
14 previous question. This finding supports not the  
15 "restaurant dining," but the "not chicken per se" point.  
16 In other words, chicken at home, the risk is lower.  
17 Chicken outside the home, the risk is higher. My point  
18 is, <sup>Why</sup> ~~why~~.

19 Q I think I'm learning. Let's fast forward.  
20 Which of these cites provide support for the italics  
21 emphasized part of that quote on page 30 of your  
22 testimony, that restaurant dining rather than chicken

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1 consumption per se appears to be the major human health  
2 threat?

3           Correct me if I'm wrong, but I think we've  
4 established that it's not Adak and it's not Friedman.  
5 I think you said it wasn't Eberhardt-Phillips, right?

6           A     Well, hold on.  If I -- if you mean the  
7 italicized portion in its entirety --

8           Q     I do.

9           A     Then I don't believe that we have established  
10 that it's not Adak.  I think Adak supports or provides  
11 some evidence in favor of its not being chicken per se.  
12 And I think that Friedman, et al., as we've just seen,  
13 indicates that chicken at home -- I admit -- we haven't  
14 gotten down to business yet, but in preliminary  
15 analysis, it suggests that chicken at home is not a  
16 risk factor and chicken outside the home is.

17                   So I don't really agree that these references  
18 aren't supporting the italicized debate.

19           Q     Am I correct that neither Adak, Friedman,  
20 Eberhart-Phillips, or Kassenborg specifically refer to  
21 restaurant dining as a risk factor?

22           A     Did you mention Friedman just then in that

1 list?

2 Q If I did not, I intended to.

3 A Friedman refers to eating outside the home  
4 rather than to restaurant dining. So if you're looking  
5 for the phrase "restaurant dining," I agree with you.

6 Q To you, as a scientist, does "outside the  
7 home" mean "restaurant"?

8 A To me, as a normal human being, "outside the  
9 home," means a superset of restaurant. It means  
10 outside the home. Restaurants are usually outside the  
11 home. But I don't equate the two.

12 MR. SPILLER: May I have a moment, Your Honor?

13 JUDGE DAVIDSON: Is this a convenient time for  
14 a break?

15 MR. SPILLER: Yes, Your Honor.

16 JUDGE DAVIDSON: We'll take a 10-minute  
17 recess.

18 MR. NICHOLAS: If I may, I request that we  
19 would adjourn this afternoon. As I mentioned,  
20 earlier --

21 JUDGE DAVIDSON: We will adjourn early. But  
22 right now, let's take a break.

1 (A brief recess was taken.)

2 MR. NICHOLAS: Your Honor, I'd like to make a  
3 request. I think that Dr. Cox is obviously eager to  
4 testify. I think if we can limit this afternoon to a  
5 half-hour, would that be a convenient break point, 30  
6 to 40 minutes from now, 3 o'clock.

7 JUDGE DAVIDSON: I was going to suggest  
8 something along those lines.

9 MR. SPILLER: That would be fine, Your Honor.  
10 And I would ask my colleagues to check me, and I take  
11 it as the understanding, the common understanding that  
12 however we restrict it today, we finish tomorrow.

13 MR. NICHOLAS: As long as we have an  
14 opportunity to redirect, we have no objection.

15 JUDGE DAVIDSON: Proceed.

16 MR. NICHOLAS: Proceed.

17 BY MR. SPILLER:

18 Q In our consideration of these papers, Dr. Cox,  
19 I don't believe I've given you yet Eberhart-Phillips,  
20 B-295, am I correct, you don't have that yet, do you?

21 A I don't believe I do.

22 MR. SPILLER: It's in the record already.

1 BY MR. SPILLER:

2 Q And just for context, Dr. Cox, this is another  
3 of the papers that you cited in support of that  
4 compound piece of your testimony. As you point out,  
5 it's compound on page 30 of your testimony, right?

6 A Correct.

7 Q Actually Eberhart-Phillips at B-295, page 5,  
8 concludes that campylobacteriosis -- and I'm on page 5,  
9 right-hand column -- is a common disease with a number  
10 of common causes, the most important being consumption  
11 of undercooked chicken. Right? That's the first  
12 sentence of their conclusion? And without me reading  
13 the record, Dr. Cox, would you agree that Dr.  
14 Kassenborg's testimony also included that she found  
15 that eating chicken or turkey at commercial  
16 establishments was the only risk factor that remained  
17 independently associated --

18 MR. NICHOLAS: Your Honor, if the witness  
19 could be provided with a copy of Dr. Kassenborg's  
20 testimony?

21 JUDGE DAVIDSON: He's absolutely entitled to  
22 see it.

1 MR. SPILLER: I'm handing the witness G-1460  
2 which is in evidence.

3 THE WITNESS: And you said she also concluded?

4 MR. SPILLER: I did.

5 THE WITNESS: Come again, please.

6 BY MR. SPILLER:

7 Q Would you refer in her testimony to page 8,  
8 lines 16 through 18? I won't read it.

9 A Yes. I'm looking at it now.

10 Q And isn't that one of her conclusions?

11 A Well, I think this is a different conclusion.  
12 You'll notice this one refers to risk factors and is  
13 specifically talking about statistical association.  
14 The Eberhart-Phillips conclusion that you just  
15 mentioned uses common causes. Campylobacteriosis is a  
16 common disease with a number of common causes, the most  
17 important being, at least for campylobacteriosis in New  
18 Zealand, the most important being the consumption of  
19 undercooked chicken. I guess it doesn't say whether  
20 it's in restaurants.

21 Now, Dr. Kassenborg -- it is not clear to me  
22 that these are the same conclusions. She is drawing a

0  
Corrected as per OR 46 6/13/03

904

1 conclusion about causes. She is drawing a conclusion  
2 about risk factors.

3 Q And both of them are drawing a conclusion  
4 about the chicken, aren't they?

5 A That's an interesting question. She may be  
6 drawing a conclusion about things correlated from  
7 chicken. In other words, saying that chicken is a risk  
8 factor. Well, being male is a risk factor. Being male  
9 is correlated with eating chicken.

10 The conclusion about a risk factor really  
11 doesn't specify the cause.

12 Q Do you think when a male eats something that  
13 contains campylobacteriosis, it's his hormones or the  
14 campylobacter that gives him campylobacteriosis?

15 A I won't speculate. I think there is probably  
16 a host of <sup>disease interaction</sup> ~~these interactions~~. But I don't know --

17 Q And the Rodriguez paper, which is G-1886 -- I  
18 don't think you have that yet.

19 A Not yet.

20 Q And by the way, whenever these piles of paper  
21 start to overwhelm you, wave at me and I will place  
22 them here and I will fetch the ones you need --

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Washington, DC 20036

(202) 467-9200

1           A     Thank you.

2           Q     And without my reading it, Dr. Cox, in  
3     Rodriguez's summary of the study, don't they identify  
4     consumption of chicken in a restaurant as statistically  
5     significantly associated with being a case that's being  
6     a case suffering from campylobacteriosis?

7           A     Let's see. There was no statistically  
8     significant risk associated with consumption of chicken  
9     other than in restaurants, nor with reported domestic  
10    kitchen hygiene factor. Is that the sentence you're  
11    referring to?

12          Q     I think the sentence that I was reading from  
13    beings at the end of the fourth line of the summary.  
14    Travel abroad and consumption of chicken in a  
15    restaurant were statistically significantly associated  
16    with being a case --

17          A     Ah.

18          Q     So the last paper in that series that you  
19    cited was the Eppler paper.

20          A     I don't follow you. You mean not last in  
21    order but last in our getting to them.

22          Q     Yes, the one that we have not yet attended to.

Corrected as per OR 46 6/13/03

906

1 And that's Exhibit G-185.

2 A Thank you.

3 Q And in the abstract, you see a sentence  
4 without my reading it that begins, "In matched logistic  
5 regression." In that exhibit on page 1, in the double  
6 indented abstract.

7 A Yes, I've found it.

8 Q The signal there that they comment on includes  
9 eating chicken prepared by a commercial food  
10 establishment in the seven days before the case illness  
11 onset as significant independent predictors of illness.  
12 Right?

13 A In their logistic <sup>regression</sup> ~~progression~~ model, yes.

14 Q And without me reading it, in the last line  
15 don't they signal that even after further study, if  
16 associated with commercially prepared chicken?

17 A Commercially prepared chicken -- I'm sorry,  
18 did you say significantly associated?

19 Q I don't believe I did in the last question. I  
20 believe I asked, didn't they say that further -- even  
21 after further study if associated --

22 A No --

1 MR. NICHOLAS: Your Honor, I'm going to  
2 object. The way this has been characterized, I believe  
3 it says further study is needed. It says, further  
4 study of the associated is needed.

5 MR. SPILLER: I stand corrected. Counsel is  
6 correct. I'll withdraw the last question.

7 THE WITNESS: I --

8 JUDGE DAVIDSON: There's no question pending.

9 BY MR. SPILLER:

10 Q So in summary, Dr. Cox, isn't it so that all  
11 of the cites that you cited for that sentence in your  
12 testimony actually support the contention that chicken  
13 consumption is associated with campylobacteriosis?

14 A Absolutely not. If you'll look at table 1 of  
15 Effler, you'll see on that on that page 3 of this  
16 exhibit you just handed me, from a restaurant there's  
17 an association in this model. For chicken eaten at  
18 home, there's a statistically significant protective  
19 effect. For cooking raw chicken at home, there's a  
20 statistically significant protective effect; the risks  
21 are down by 50 percent. For touching any raw chicken  
22 at home, there's a statistically significant reduction.

Corrected as per OR 46 6/13/03

908

1 Your risks are only .6 of what they otherwise would  
2 have been.

3 For turkey, well, turkey looks marginally  
4 different. And then we have ham and beef and so forth.  
5 The italicized statement was that restaurant dining  
6 rather than chicken consumption, per se, appears to be  
7 the major human health threat for CP,  
8 campylobacteriosis. And I believe that each of the  
9 sources drawn from provides substantial evidence to  
10 support that.

11 Q Did I understand you correctly just now, Dr.  
12 Cox, to say it was protective for eating chicken  
13 outside the home?

14 A I don't remember my words, but I did mean that  
15 the ~~math~~ <sup>matched</sup> odds ratio is statistically significantly  
16 smaller for those who've eaten chicken at home, cooked  
17 chicken at home, touched raw chicken at home and so  
18 forth, than for people who have not.

19 Q You can help me understand this then. We're  
20 looking at Effler, page 3, table 1, under dietary or  
21 environmental exposure, top line, chicken eaten outside  
22 the home.

1 A Yes.

2 Q Fifty-four percent of the patients and 38  
3 percent of the controls there, with an odds ratio of 2.  
4 Am I right that more patients than controls were --

5 A Ate chicken outside the home, yes. And solely  
6 from a restaurant.

7 Q And so both of those do associate the  
8 consumption of chicken in those circumstances with  
9 campylobacteriosis?

10 A They associate consumption of something  
11 outside the home, and that something can be chicken.  
12 That something, if you look down at ham, can be ham.  
13 If you look down to steak or to -- actually not steak.  
14 Steak is protective. So ham is a better example.

15 But to get at what chicken, per se, chicken by  
16 itself causes, I think you have to go beyond these  
17 associations and look at the data, which I've been able  
18 to do for Effler, which I've been able to do for  
19 Friedman. That's where you find out what's really  
20 going on.

21 Q And without my pestering you with it, Effler's  
22 conclusions are recorded in this table 1?

1           A     Some of his I think most important  
2 quantitative conclusions are in table 1. Not in his  
3 abstract, which is in his summary, but yes, in table 1.

4           Q     So where you and he disagree, you would  
5 suggest that we go with Cox on the Effler study, or go  
6 with Effler on the Effler on the Effler study?

7           A     I would recommend starting with the Effler  
8 data and using generally accepted and commercial  
9 programs and seeing what they say.

10          Q     And do you suggest that he did not?

11          A     I suggest -- I state that he used a particular  
12 model conditional logistic progression without  
13 reporting the standard model diagnostics and tests that  
14 would roughly correspond to what I just said. He  
15 didn't quantify model uncertainty, he didn't specify  
16 how variable testing was done. So I think there are a  
17 number of statistical limitations to this analysis.  
18 However -- well, and I'll stop there.

19          Q     Let's turn to another of the recurring cites  
20 in your testimony, the Rosenquist paper. It's G-1788.  
21 That one, I believe you cite 11 times in your  
22 testimony. Does that sound approximately correct?

1 A Yes. Yes. Thank you.

2 Q In your discussion of the Effler paper, Dr.  
3 Cox, do I understand that you think it's important to  
4 explicitly treat the issue of uncertainty?

5 A I think it's important to account for the  
6 issue of uncertainty, yes.

7 Q Thank you. Referring to your testimony, page  
8 15, in the last paragraph, the last sentence, you're  
9 teaching me to be careful about these citations. I  
10 think you seem to say that Rosenquist supports that  
11 sentence. Am I understanding that correctly?

12 A Yes. It's my belief, which I have a feeling  
13 we're about to test, that Rosenquist has stated,  
14 without completing hazard identification, that we're  
15 going to assume there's a risk. Yes.

16 Q And that connection is simply assumed and is  
17 not present in the data. That's what you said.

18 A Yes.

19 Q So let's look at Rosenquist page 3 -- sorry,  
20 I'll let you finish your answer.

21 A I was going to say, yes, but there's some  
22 ambiguity in my mind on exactly how to parse this

*Corrected as per OR 46 6/13/03*

912

1 sentence, which I hope won't be relevant. The question  
2 is, it is not present in the data. Did Rosenquist say  
3 that? Or did Rosenquist simply support the assumption?  
4 Rosenquist just said, hey, we're going to assume  
5 there's risk in the analysis, or did he go further and  
6 say I looked at the data -- but I'm not sure, as I sit  
7 here, whether he looked at the data or whether he said,  
8 we're just going to assume that it's there.

9 Q Well, let's check. Let's look at Rosenquist,  
10 G-1788, page 3, the right-hand column. And this one  
11 long paragraph that begins with the number of the  
12 human -- and would you read to yourself the next  
13 sentence that begins, "the high prevalence," that ends  
14 with, and I'd like you to count these, 12 references.

15 A Okay.

16 Q They have 12 references for the support that  
17 chickens play an important role in the transfer of  
18 campylobacter in humans?

19 A No, it's "seem to support".

20 Q And did Rosenquist, et al., distinguish that  
21 seeming support from real support in their paper?

22 A Are you asking what they meant by seeming to

1 support?

2 Q No. I'm asking did they distinguish, as I  
3 understood your last answer, between seem to support  
4 and actually support? Do they say anywhere in this  
5 paper that those 12 references only seemed to support?

6 A They say that right there. I'm sorry, am I  
7 being unresponsive?

8 Q No, I'm not being precise enough. Did you  
9 read those papers?

10 A I have read through some -- I have read  
11 through some of them lightly, some of them more  
12 carefully, most of them. The only ones I have really  
13 studied are the ones where I can put my hands on the  
14 data.

15 Q While we're on the Rosenquist study, Dr. Cox,  
16 I'd like to show you one of the citations of that.

17 MR. SPILLER: Your Honor, this will take me a  
18 moment to set up, if I can do it efficiently.

19 JUDGE DAVIDSON: The witness is starting to  
20 fade. Do you want to break here?

21 MR. SPILLER: That's fine with me, Your Honor.

22 JUDGE DAVIDSON: Okay, I accede to your

1 request.

2 THE WITNESS: Thank you.

3 JUDGE DAVIDSON: You are excused today. You  
4 will be back tomorrow.

5 THE WITNESS: Thank you.

6 (The witness was excused.)

7 JUDGE DAVIDSON: And we have a little bit of  
8 housekeeping to take care of.

9 Have you had a chance to confer about the FOI  
10 requests and responses, et cetera, and whether you want  
11 them in or out?

12 MR. NICHOLAS: No, we haven't, Your Honor. We  
13 wanted to speak to you first thing in the morning.

14 JUDGE DAVIDSON: That's my deal. All or  
15 nothing. Now, we've got response to -- were you  
16 supposed to give me a response to something else, or is  
17 that the same area?

18 MS. STEINBERG: We do have two other matters I  
19 have a response, if I may approach to hand you a copy.  
20 I'll be filing this with dockets this afternoon. It is  
21 CVM's opposition to the entry into the evidentiary  
22 records of two documents of six that were moved by

1 Bayer --

2 JUDGE DAVIDSON: Okay, so you don't have to --  
3 sorry, you do it your way. That's fine.

4 The record of this proceeding is every bit as  
5 good as the written order from me. So I won't repeat  
6 the order insofar as it pertains to the 1924, 1925,  
7 1926, and 1927. I'm allowing them in. You don't have  
8 an objection, so they will be in the record as  
9 received.

10 (Respondent Exhibits 1924  
11 through 1927 were marked for  
12 identification and received in  
13 evidence.)

14 JUDGE DAVIDSON: All right, you want to file  
15 this, your objection, and I'll rule on it.

16 MS. STEINBERG: Thank you, Your Honor.

17 JUDGE DAVIDSON: Is there a B-1935?

18 MR. KRAUSS: Your Honor, may I clear that up  
19 tomorrow? B-1935 may have been something that we  
20 marked yesterday.

21 JUDGE DAVIDSON: Doesn't matter; I just wanted  
22 to make sure I didn't miss it, that's all.

1 MR. KRAUSS: I will clear it up tomorrow, Your  
2 Honor.

3 JUDGE DAVIDSON: Now, is there a G-1805?

4 MR. SPILLER: I don't believe there is, Your  
5 Honor, but I'm not positive. I will try to --

6 JUDGE DAVIDSON: They're just gaps in the  
7 numbers. I don't mind if you miss a number; I've just  
8 got to make sure I didn't miss an exhibit somewhere.

9 MR. SPILLER: I think it's a missing number,  
10 Your Honor. We skipped to make sure that we didn't --

11 JUDGE DAVIDSON: That's okay. That's all  
12 right. And tomorrow morning, you're going to let me  
13 know what you think about the 1804? What about 1801?  
14 What did we do with that? Were we supposed to respond  
15 to that today? Did you already respond?

16 MR. NICHOLAS: Your Honor, if I may, 1801 is  
17 the one that we responded to yesterday afternoon with a  
18 reply --

19 JUDGE DAVIDSON: That's in the FOI business?

20 MR. NICHOLAS: That's correct, Your Honor.

21 JUDGE DAVIDSON: So is 1804, though. Because  
22 I ruled it out, but it seems to me that was a response

1 of somebody in the Agency. That was a FOI one too.

2 All right, 1801 is also, right?

3 MR. NICHOLAS: I believe so, Your Honor.

4 JUDGE DAVIDSON: It's still all or nothing.

5 So we'll wait until what you decide tomorrow. They'll  
6 be in or out, but they'll certainly stay in the  
7 administrative record.

8 MS. ZUCKERMAN: Your Honor, may I just make  
9 one comment about --

10 JUDGE DAVIDSON: My behavior? Sure. Go  
11 ahead.

12 MS. ZUCKERMAN: No, Your Honor. As I  
13 understood your direction this morning, the in or out  
14 ruling is based on the fact that Bayer's motion  
15 yesterday dealt with FOIA-related documents. However,  
16 the motion and all the attachments, which I think are  
17 over a thousand pages, actually include four  
18 declarations, several of which attempt to change  
19 testimony that's been filed in this proceeding. So to  
20 attempt to address those --

21 JUDGE DAVIDSON: Which exhibit are we talking  
22 about?

1 MS. ZUCKERMAN: These are Exhibits B-1938, B-  
2 1939, those are declarations from two Bayer witnesses  
3 changing their testimony. And B-1940 and 1941 are from  
4 Bayer employees, Bayer counsel.

5 I have drafted a two-page opposition under the  
6 belief that we had to submit something today.

7 JUDGE DAVIDSON: Well, you did. You said you  
8 were going to, to those. But I was concerned -- maybe  
9 I misread it, but I thought we were talking about the  
10 FOI request. Now --

11 MS. ZUCKERMAN: We were. Except, attached to  
12 that, Bayer's opposition, was a motion to introduce  
13 these --

14 JUDGE DAVIDSON: New exhibits? They were  
15 declarations?

16 MS. ZUCKERMAN: Yes. And -- four  
17 declarations, four or five into the evidentiary record.

18 JUDGE DAVIDSON: I'll have to look at them  
19 again. I don't recall them being anything more than  
20 with respect to the FOI stuff. If I'm wrong, I will  
21 change that.

22 MR. NICHOLAS: Your Honor, if I may, they are

Corrected as per OR 46 6/13/03

919

1 all related to the FOI stuff. When we received the  
2 files from CDC in the what's called SAS format, we  
3 compared those files with the files we had previously  
4 received from CDC and when we compared those files, we  
5 noticed there were some discrepancies between  
6 particular files that some witnesses had based  
7 testimony on. And so we moved to withdraw in those  
8 declarations those portions of the testimony that were  
9 deemed inaccurate as a result of being provided  
10 inaccurate files by CDC.

11 MS. ZUCKERMAN: If I may, Your Honor,  
12 actually, that's true up to a point. There is one  
13 declaration that purports not only to withdraw certain  
14 portions of testimony, but to actually change the  
15 testimony that's been submitted and ~~resubmitted in~~ *resubmit it in a*  
16 paragraph. May I file these now?

17 JUDGE DAVIDSON: Certainly. You can file  
18 whatever you want to file. You're just leading me more  
19 into the conclusion that everything should be out  
20 rather than in. Because it stays in the administrative  
21 file.

22 And as I said, I think you'll recall when we

1 had that informal conference on the telephone, that  
2 your request, Mr. Nicholas, after you found out that  
3 it's provided in different formats, I'm pretty sure I  
4 said to you at that time, if you find specific areas  
5 that have caused you a problem because the information  
6 provided was either not available or was misleading or  
7 not subject to interpretation, that I wanted to know  
8 about the specifics of what was involved. And I didn't  
9 hear anything.

10 MR. NICHOLAS: Your Honor, we got those files.  
11 It took us some time --

12 JUDGE DAVIDSON: I know. I understand. But  
13 I'm saying, the same -- even though that was off the  
14 record and it was procedural only, the same thing  
15 applies.

16 If there is a specific reason to change  
17 something based on the fact that you didn't get the  
18 information in the proper format or for whatever other  
19 reason, then I want to know specifically about that  
20 now.

21 In your request, taking representations of  
22 counsel, that there was one of the requests more than

1 just deleting things, it was adding something.

2 MR. NICHOLAS: Your Honor, I believe what's  
3 contained in the motion that we filed yesterday are the  
4 declarations to trace the chain of custody, if you  
5 will.

6 When we received the CDC files initially in  
7 this Excel format, when we received the SAS files from  
8 CDC, how we went about trying to match them up together  
9 and, as a result of that, what testimony we believed  
10 was incorrect as a result of that.

11 And I do believe in one instance that  
12 testimony has addressed what the discrepancy was and  
13 how it would change the testimony. I don't believe it  
14 represents the testimony here.

15 JUDGE DAVIDSON: That's what I'm going to have  
16 to decide, I guess.

17 Do you think you covered it sufficiently in  
18 your motion?

19 MR. NICHOLAS: Yes, I do, Your Honor.

20 JUDGE DAVIDSON: Okay, and I've got a  
21 response. I'll work on it.

22 MS. ZUCKERMAN: Thank you, Your Honor.

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MR. NICHOLAS: Thank you, Your Honor.

JUDGE DAVIDSON: Okay, we're adjourned until  
9:00 a.m. tomorrow morning.

(Whereupon, at 2:50 p.m., the hearing was  
adjourned, to reconvene Wednesday, May 7, 2003 at 9:00  
a.m.)

\* \* \* \* \*